

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

March 16, 1999

OFFICE OF PREVENTION, PESTICIDES AND **TOXIC SUBSTANCES**

MEMORANDUM

Subject:

Efficacy Review and Label Review for "Permacide Brand (Ristex)

Germicidal Disinfectant Solution" EPA Reg. No. 8383-3. Case No. 012866

DP Barcode: D250927

From:

Bruce H. Mann

Efficacy and Science Support Branch

Efficacy Evaluation Team

Antimicrobial Division (7510C)

To:

Thru:

Adam Heyward, PM 34/Portia Jenkins Regulatory Management Branch II Antimicrobial Division (7510C)

John W. Newland, Ph.D., J.D., Team Leader

Efficacy Evaluation Team

Efficacy and Science Support Branch Antimicrobial Division (7510C)

Michele E. Wingfield, Chief

Efficacy and Science Support Branch

Antimicrobial Division (7510C

Applicant: Sporicidin International

5901 Montrose Road

Rockville, Maryland 20852

Formulation From Label

Active Ingredient(s)	% by w
Phenol	1.56
Sodium Phenate	
Inert Ingredient(s)	
Total	

LABELING:

The following comments are applicable for the proposed label pinpunched and dated 10-02-98. See attached.

- 1. On the back left panel, 2nd paragraph, last sentence, revise the wordings "Reduces the hazards of cross-contamination on hard surfaces" to read "Reduces the hazards of cross-contamination on hard, nonporous surfaces".
- 2. On the back left panel, 5th paragraph, revise the phrase "...and *Polio type 1 viruses*..." to read "...and *Polio type 1 viruses* on hard nonporous, inanimate surfaces...". In the same paragraph, and after the words "...and *Mycobacterium tuberculosis* in ten minutes..." add "... at 20°C ...".
- 3. On the back left panel, 5th paragraph, and following the contact time "...in three minutes..." add "... on hard nonporous surfaces..."..
- 4. On the back left panel, 5th paragraph, and following the contact time of "...in one minute..." add "...on hard, nonporous, surfaces...".
- 5. A label clarification should be provided as to what species of *Herpes simplex virus* is the causative agent of the eye condition "...ocular...". We need to know the exact nomenclature as listed or indicated in the "ATCC Catologue".

BACKGROUND:

The subject product "Sporicidin Brand (Ristex) Germicidal Disinfectant" is registered as a disinfectant for use in hospitals, medical offices, nursing homes, schools, trains, boats, resturants, autos, health spas and toilets. Also, the product's labeling contains claims which are reported to be fungicidal, tuberculocidal, virucidal, and bactericidal. For other additional uses, refer to the product last accepted label dated 06-05-95.

The current submission is an amendment to revise the product's 10 minute exposure time to an exposure time of 3 minutes for the below listed microorganisms. This proposed decrease in exposure time is proposed for the following microorganisms: Staphylococcus aureus (ATCC 6538), Salmonella choleraesuis (ATCC 10708), Pseudomonas aeruginosa (ATCC 15442), and Trichophyton mentagrophytes (ATCC 9533).

The present submission contains microbiological efficacy data (mrid #446778-01) and a proposed label in support of the decreased exposure time. All data reports and proposed labeling are reviewed and summarized below.

RECOMMENDATIONS:

EFFICACY SUPPORTED by the SUBMITTED DATA:

The submitted microbiological data developed by the AOAC Germicidal Spray
Tests Method are adequate and supportive of the product effectiveness as a spray
disinfectant (ready-to-use solution) in the presence of a moderate amount of soil (5% horse serum) for
hard, nonporous, inanimate surfaces when thoroughly wetted by the spray
and allowed to remain wet for an exposure time of 3 minute.

Effectiveness was demonstrated against Salmonella choleraesuis (ATCC 10708), Staphylococcus auresus (ATCC 6538), and Pseudomonas aeruginosa (ATCC 15442).
Refer to attachment #1.

The submitted fungicidal data are supportive of the product as a fungicide against pathogenic fungi (*Trichophyton mentagrophytes*) for hard, nonporous, inanimate surfaces when thoroughly wetted by the spray disinfectant (ready-to-use solution) and allowed to remain wet for an exposure time of at least 3 minutes.

Effectiveness was demonstrated against *Trichophyton mentagrophytes* (ATCC 9533). Refer to attachment #1.

HOSPITAL DISINFECTION



24

An effective cleaner, disinfectant and active deodorant for hospitals, clinics, medical and veterinary offices, laboratories, industrial clean rooms, homes, nursing homes, ambulances, hotels, restaurants, schools, airplanes, trains, boats, autos, buses, health spas and toilets.

DISINFECTANT: Acts effectively on germ laden non-porous equipment and surfaces in medical treatment and patient rooms, operating rooms, emergency rooms, recovery rooms and bathrooms. For use on medical and dental equipment, beds, surgical carts, counter tops, manikins, telephones, furniture, wheelchairs, walkers, sinks, floors, walls, light switches, linen hampers, shower stalls, tollet seats, trash containers and damp and musty areas, including animal enclosures. Reduces the hazards of cross-contamination hard surfaces.

ACTIVE DEODORIZER*: Provides continuous residual bacteriostatic activity against odor-causing organisms for up to 6 months in the presence of adequate moisture, if not removed from surfaces including plastics, latex, vinyl, glass, wood, metal, porcelain, tile and paint.

Kills Athlete's Foot fungus on bathroom, shower and pool surfaces
 Penetrates cracks • Non-staining • Contains no harmful abrasives • Self-sanitizes surfaces against odor-causing bacteria.

SPORICIDIN Brand DISINFECTANT SOLUTION is germicidal when used as directed for disinfection but differs in composition from offer Sporicidin products.

PASSES AUAG EFFICACY STANDARDS FOR INSTITUTIONAL AND HOSPITAL DISINFECTION including Staphylococcus aureus, Streptococcus pyogenes, Streptococcus salivarius, Salmonella choleraesuis, Pseudomonas aeruginosa, Escherichia coli, **Herpes simplex types 1 and 2 (oral, ocular, and genital), influenza A. (Japan 305/57 Asian strain),

and genital), Influenza A. (Japan 305/57 Asian strain), Vaccinia, Canine parvovirus, Cytomegalovirus, Coronavirus and Polio type 1 viruses, Trichophyton mentagrophytes (Athlete's Foot fungus), Mycobacterium tuberculosis and HIV-1 (AIDS virus) on hard surfaces.

DIRECTIONS FOR USE: It is a violation of U.S. Federal Law to use this product in a manner inconsistent with its labeling.

PRECLEAN instruments and other surfaces with Sporicidin Brand Disinfectant Solution to remove soil and fitth. Wipe dry with paper towel, cloth or soonce.

TO DISINFECT AND DEODORIZE: Thoroughly wet pre-cleaned surface with disinfectant. Allow 10 minute contact time at room temperature (20°C/68°F or above). NOTE: See Sporicidin Bulletin No. 303 for HIV-1 (AIDS virus) instructions

TO PREVENT MOLD AND MILDEW: Repeat application weekly, or sooner if new growth appears.

FOR FOGGING CLEAN ROOMS: See Sporicidin Bulletin No. 301.

TO CLEAN AIR DUCTS: Manually apply to hard, non-porous, precleaned duct surfaces. Filnse surfaces after application.

PRECAUTIONARY STATEMENTS: Hazard to Humans and Domestic Animals.

CAUTION: Avoid direct food contact. Avoid eye contact, in case of contact, immediately flush with water. If necessary, consult a physician.

STORAGE AND DISPOSAL: Store at room temperature. Discard empty container in regular trash.

NOTE: This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally

sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

6352

change to read

Kills vegetative organisms including Streptococcus pyogenes, Streptococcus salivarius, Escherichia coli, **Herpes simplex types 1 and 2 (oral, ocular and genital), Influenza A₂ (Japan 305/57 Asian strain), Vaccinia, Canine parvovirus, Cytomegalovirus, Coronavirus and Polio type 1 viruses, and Mycobacterium tuberculosis in ten minutes.

INTERNATIONAL

Rockville, MD 20852

Kills Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa and Trichophyton mentagrophytes (Athlete's Foot fungus) in three minutes.

Kills HIV-1 (AIDS virus) in one minute

See attashed Bulleti

D= location of required changes

#5

Sporicidin

BULLETIN NOS. 303 and 403

SPECIAL INSTRUCTIONS
FOR
CLEANING AND
DECONTAMINATION OF
SURFACES/OBJECTS
SOILED WITH
BLOOD/BODY FLUIDS
AGAINST
HIV-1 (AIDS VIRUS)

SPORICIDIN BULLETIN NO. 303:

Sporicidin Brand
Disinfectant Solution and Towelette
(EPA Reg. Nos. 8383-3 and 8383-7)

a. Personal Protection:

Persons handling items soiled with blood or body fluids likely to be contaminated with HIV-1 (AIDS virus) must protect themselves by use of disposable latex gloves, gowns, masks and eye covering.

b. Decontamination of Contaminated Objects:

Immediately after use, items contaminated with blood, body fluids, or other soils that may contain HIV-1 (AIDS virus) must be thoroughly wetted with Sporicidin brand disinfectant solution or towelette for at least 1 minute before further processing.*

c. Cleaning Procedure:

Following decontamination, objects and surfaces are moved to the cleaning and preparation areas where they are washed; rinsed and rough dried to remove all blood and body fluids before application of the disinfectant.

d. Contact Time for Disinfection:

Thoroughly wet entire object or surface with solution or towelette. HIV-1 (AIDS virus) is killed within 1 minute contact time. Note: Use a 10 minute contact time for other organisms. This product should not be used for disinfection of critical or semi-critical items.

e. Disposal of Infectious Materials:

Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

SPORICIDIN BULLETIN NO. 403:

Sporicidin Brand Disinfectant Spray (EPA Reg. No. 8383-4)

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b. Decontamination of Contaminated Objects:

Immediately after use, items contaminated with blood, body fluids, or other soils that may contain HIV-1 (AIDS virus) must be sprayed to thoroughly wet with disinfectant for 1 minute before further processing.

c. Cleaning Procedure:

Following decontamination, objects and surfaces are moved to the cleaning and preparation area where they are washed; insed and rough dried to remove all blood and body fluids before application of the disinfectant.

d. Contact Time for Disinfection:

Spray to thoroughly wet entire object or surface. HIV-1 (AIDS virus) is killed within 1 minute contact time. "Note: Use a 10 minute contact time for other organisms. This product should not be used for disinfection of critical or semi-critical items.

e. Disposal of Infectious Materials:

Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

FRONT LABEL - NO CHANGE





DISINFECTANT SOLUTION

PRESOAK AND DISINFECTANT

- BACTERICIDAL
- VIRUCIDAL**
- FUNGICIDAL
- TUBERCULOCIDAL

Active Ingredients

 EPA Reg. No. 8383-3 EPA Est. No. 034346-NB-001 Net Conténts: 1 U.S. Gal. (3.79 ltr.)

Keep Out of Reach of Children CAUTION

See additional precautions on back panel

Sporicidin

BULLETIN NOS. 303 and 403

SPECIAL INSTRUCTIONS
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- c. Cleaning Procedure:

Following decontamination, objects and surfaces are moved to the cleaning and preparation areas where they are washed; rinsed and rough dried to remove all blood and both fluids before application of the disinfectant.

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Sodium Phenate0.06% Inert Ingredients98.38% EPA Reg. No. 8383-3 EPA Est. No. 034346-NB-001 Net Contents: 1 U.S. Gal. (3.79 ltr.)

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Sporicidin

BULLETIN NOS. 303 and 403

SPECIAL INSTRUCTIONS FOR **CLEANING AND DECONTAMINATION OF** SURFACES/OBJECTS **SOILED WITH BLOOD/BODY FLUIDS AGAINST** HIV-1 (AIDS VIRUS)

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98.38%

HOSPITAL DISINFECTION



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ACTIVE DEODORIZER*: Provides continuous residual bacteriostatic activity against odor-causing organisms for up to 6 months in the presence of adequate moisture, if not removed from surfaces including plastics, latex, vinyl, glass, wood, metal, porcelain, tile and paint.

Kills Athlete's Foot fungus on bathroom, shower and pool surfaces
 Penetrates cracks • Non-staining • Contains no harmful abrasives • Self-sanitizes surfaces against odor-causing bacteria.

SPORICIDIN Brand DISINFECTANT SOLUTION is germicidal when used as directed for disinfection but differs in composition from other Sporicidin products.

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DIRECTIONS FOR USE: It is a violation of U.S. Federal Law to use this product in a manner inconsistent with its labelling.

PRECLEAN instruments and other surfaces with Sporicidin Brand Disinfectant Solution to remove soil and filth. Wipe dry with paper towel, cloth or sponge.

TO DISINFECT AND DEODORIZE: Thoroughly wet pre-cleaned surface with disinfectant. Allow 10 minute contact time at room temperature (20°C/68°F or above). NOTE: See Sporicidin Bulletin No. 303 for HIV-1 (AIDS virus) instructions.

TO PREVENT MOLD AND MILDEW: Repeat application weekly, or sooner if new growth appears.

FOR FOGGING CLEAN ROOMS: See Sporicidin Bulletin No. 301.

TO CLEAN AIR DUCTS: Manually apply to hard, non-porous, precleaned duct surfaces. Rinse surfaces after application.

PRECAUTIONARY STATEMENTS: Hazard to Humans and Domestic Animals.

CAUTION: Avoid direct food contact. Avoid eye contact. In case of contact, immediately flush with water. If necessary, consult a physician.

STORAGE AND DISPOSAL: Store at room temperature. Discard empty container in regular trash.

NOTE: This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally

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6352

change to read

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and Polio type 1 viruses, and Mycobacterium tuberculosis in ten minutes.

Sporicidin

EINTERNATIONAL Rockville, MD 20852

• Kills Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa and Trichophyton mentagrophytes (Athlete's Foot fungus) in three minutes.

Kills HIV-1 (AIDS virus) in one minute.

Frewiously accepted - "
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Presoak Disinfect

HOSPITAL DISINFECTION

INTERNATIONAL

Rockville, MD 20852



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Kills vegetative organisms including Streptococcus pyogenes, Streptococcus salivarius, Escherichia coli, **Herpes simplex types 1 and 2 (oral and genital), Influenza A; (Japan 305/57 Asian strain), Vaccinia, Canine pervovirus, Cytomegalovirus, Coronavirus and Polio type 1 viruses, and Mycobacterium telescalosis in ten minutes.

Kills Staphylococcus sureus, Salmonella choleraesuis, Psendomonas

Kills Staphylococcus sureus, Salmonella cholecaesuis, Pseudomonas acruginosa and Trichophyton mentagrophytes (Athlete's Foot fungus) in three minutes.

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6352





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Kills Staphylococcus aureus, Salmonella cholemesuis, Pseudomonas acruginosa and Trichophyton meetagrophytes (Athlete's Foot fungus) in three minutes.

Kills HIV-1 (AIDS virus) in one minute.

DIRECTIONS FOR USE: It is a violation of U.S. Federal Law to use this product in a manner inconsistent with its labeling.

PRECLEAN instruments and other surfaces with Sporicidin Brand Disinfectant Solution to remove soil and filth. Wipe dry with paper towel, cloth or sponge.

TO DISINFECT AND DEODORIZE: Thoroughly wet pre-cleaned surface with disinfectant. Allow 10 minute contact time at room temperature (20°C/68°F or above). NOTE: See Sporicidin Bulletin No. 303 for HIV-1 (AIDS virus) instructions.

TO PREVENT MOLD AND MILDEW: Repeat application weekly, or sooner if new growth appears.

FOR FOGGING CLEAN ROOMS: See Sporicidin Bulletin No. 301.

TO CLEAN AIR DUCTS: Manually apply to hard, non-porous, precleaned duct surfaces. Rinse surfaces after application.

PRECAUTIONARY STATEMENTS: Hazard to Humans and Domestic Animals.

CAUTION: Avoid direct food contact. Avoid eye contact. In case of contact, immediately flush with water. If necessary, consult a physician.

STORAGE AND DISPOSAL: Store at room temperature. Discard empty container in regular trash.

NOTE: This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally

sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

6352

ENTERNATIONAL
Rockville, MD 20852



HOSPITAL DISINFECTION



An effective cleaner, disinfectant and active deodorant for hospitals, clinics, medical and veterinary offices, laboratories, industrial clean rooms, homes, nursing homes, ambulances, hotels, restaurants, schools, airplanes, trains, boats, autos, buses, health spas and toilets.

DISINFECTANT: Acts effectively on germ laden non-porous equipment and surfaces in medical treatment and patient rooms, operating rooms, emergency rooms, recovery rooms and bathrooms. For use on medical and dental equipment, beds, surgical carts, counter tops, manikins, telephones, furniture, wheelchairs, walkers, sinks, floors, walls, light switches, linen hampers, shower stalls, toilet seats, trash containers and damp and musty areas, including animal enclosures. Reduces the hazards of cross-contamination on hard surfaces.

ACTIVE DEODORIZER*: Provides continuous residual bacteriostatic activity against odor-causing organisms for *up to 6 months* in the presence of adequate moisture, if not removed from surfaces including plastics, latex, vinyl, glass, wood, metal, porcelain, tile and paint.

Kills Athlete's Foot fungus on bathroom, shower and pool surfaces
 Penetrates cracks • Non-staining • Contains no harmful abrasives • Self-sanitizes surfaces against odor-causing bacteria.

SPORICIDIN Brand DISINFECTANT SOLUTION is germicidal when used as directed for disinfection but differs in composition from other Sporicidin products. PASSES AUAG EFFICACY STANDARDS FOR INSTITUTIONAL AND HOSPITAL DISINFECTION

Kills vegetative organisms including Streptococcus pyogenes, Streptococcus salivarius, Escherichia coli, **Herpes simplex types 1 and 2 (oral and genital), Influenza A₂ (Japan 305/57 Asian strain), Vaccinia, Camine pervovirus, Cytomegalovarus, Coronavirus and Polio type 1 varuses, and Mycobacterium to emplosis in ten minutes.

Sportcidin

Kills Staphylococcus aureus, Salmonella cholernesuis, Pseudomonas aeruginosa and Trichophyton mentagrophytes (Athlete's Foot fungus) in three minutes.

Kills HIV-1 (AIDS virus) in one minute.

DIRECTIONS FOR USE: It is a violation of U.S. Federal Law to use this product in a manner inconsistent with its labeling.

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TO DISINFECT AND DEODORIZE: Thoroughly wet pre-cleaned surface with disinfectant. Allow 10 minute contact time at room temperature (20°C/68°F or above). NOTE: See Sporicidin Bulletin No. 303 for HIV-1 (AIDS virus) instructions

TO PREVENT MOLD AND MILDEW: Repeat application weekly, or sooner if new growth appears.

FOR FOGGING CLEAN ROOMS: See Sporicidin Bulletin No. 301.

TO CLEAN AIR DUCTS: Manually apply to hard, non-porous, precleaned duct surfaces. Rinse surfaces after application.

PRECAUTIONARY STATEMENTS: Hazard to Humans and Domestic Animals.

CAUTION: Avoid direct food contact. Avoid eye contact, in case of contact, immediately flush with water. If necessary, consult a physician.

STORAGE AND DISPOSAL: Store at room temperature. Discard empty container in regular trash.

NOTE: This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally

sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

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Rockville, MD 20852





INTERNATIONAL

Rockville, MD 20852



An effective cleaner, disinfectant and active deodorant for hospitals, clinics, medical and veterinary offices, laboratories, industrial clean rooms, homes, nursing homes, ambulances, hotels, restaurants, schools, airplanes, trains, boats, autos, buses, health spas and toilets.

DISINFECTANT: Acts effectively on germ laden non-porous equipment and surfaces in medical treatment and patient rooms, operating rooms, emergency rooms, recovery rooms and bathrooms. For use on medical and dental equipment, beds, surgical carts, counter tops, manikins, telephones, furniture, wheelchairs, walkers, sinks, floors, walls, light switches, linen hampers, shower stalls, toilet seats, trash containers and damp and musty areas, including animal enclosures. Reduces the hazards of cross-contamination on hard surfaces.

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Kills Staphylococcus sureus, Salmonella choleraesuis. Pseudomones*

Kills Staphylococcus sureus, Salmonella choleraesuis, Pseudomonas acruginosa and Trichophyton mentagrophytes (Athlete's Foot fungus) in three minutes.

Kills HIV-1 (AIDS virus) in one minute.

DIRECTIONS FOR USE: It is a violation of U.S. Federal Law to use this product in a manner inconsistent with its labeling.

PRECLEAN instruments and other surfaces with Sporicidin Brand Disinfectant Solution to remove soil and filth. Wipe dry with paper towel, cloth or sponge.

TO DISINFECT AND DEODORIZE: Thoroughly wet pre-cleaned surface with disinfectant. Allow 10 minute contact time at room temperature (20°C/68°F or above). NOTE: See Sporicidin Bulletin No. 303 for HIV-1 (AIDS virus) instructions.

TO PREVENT MOLD AND MILDEW: Repeat application weekly, or sooner if new growth appears.

FOR FOGGING CLEAN ROOMS: See Sporicidin Bulletin No. 301.

TO CLEAN AIR DUCTS: Manually apply to hard, non-porous, precleaned duct surfaces. Rinse surfaces after application.

PRECAUTIONARY STATEMENTS: Hazard to Humans and Domestic Animals.

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HOSPITAL DISINFECTION

Rockville, MD 20852



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